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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/383,054	08/25/1999	DAVID A. EDWARDS	AIR-108PA	6042

7590 08/04/2003  
ELMORE CRAIG, P. C.  
209 MAIN STREET  
NO. CHELMSFORD, MA 01863

EXAMINER

PULLIAM, AMY E

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 08/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/383,054

Applicant(s)

EDWARDS ET AL.

Examiner

Amy E Pulliam

Art Unit

1615

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 24 June 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 19 May 2003. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: \_\_\_\_\_.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

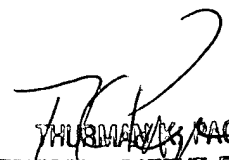
Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 52-69, 92-108, 128-131.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_.

Continuation of 2. NOTE: Applicant has requested reconsideration of the amendment proposed in paper number 22, filed May 19, 2003. This amendment narrowed the claims to the transitional language "consisting of" rather than the broader language used previously. Applicant argues that Durrani does not focus on nor address the special problems arising with protein stability when spray drying. Applicant further argues that all of Durrani's working examples include additional ingredients, in addition to the phospholipid and the protein. This argument is not found to be persuasive. The scope of a teaching does not necessarily depend on the working examples. The examiner points to claim 1 of the reference, which teaches a process of spray drying a drug/lipid powder by mixing the drug, the lipid and a solvent. This is exactly the same method claimed by Applicant. There is nothing present in this claim 1 of the reference which requires any additional additives. Furthermore, it is not until claim 8 that an additional component is even mentioned in the reference. Additionally, Applicant has provided no unexpected results stemming from the exclusion of normal excipients in a pharmaceutical formulation. In fact, in their specification, Applicant has provided details on including excipients in the formulation. It is recommended that Applicant provide analysis discussing any unexpected results provided by the instant claims when compared to the prior art. The claims, as drafted, are very broad. They require only a teaching to spray drying a protein, a phospholipid and a solvent. Claim 1 of Durrani clearly teaches this method, because even if the working examples disclose additional limitations, the claims do not require any. Therefore, the prior rejections are maintained..

  
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